

# **ALL Categories**

## **General:**

### **General-Appeals**

#### **General-Appeals**

##### **question**

Do establishments need to file an appeal of an NR in less than 48 hours of the date of the NR?

##### **answer**

The regulations for poultry (381.35) state "...provided that such appeal is filed within 48 hours from the time the decision is made." However, the ultimate decision regarding the timeliness of appeals lies with the District Manager. Additionally, there is no established time frame for appeals in red meat establishments, but the appeal should be made in a timely manner.

#### **General-Appeals**

##### **question**

When I am going to appeal an NR, do I need to write a response first or wait until after my appeal is heard.

##### **answer**

You do not need to write a response on an NR. You must take corrective action on the product/situation and provide preventive measures, but you do not need to write a response. An establishment has the right to appeal at any time.

### **General- ISP Codes**

#### **General-ISP Codes**

##### **question**

FSIS Directive 11,000.1 VII says that 06D02 was consolidated with 06D01 but it comes up on my Procedure Schedule. Should I try to get the District Office to delete it?

##### **answer**

No, 06D02 is a viable ISP code. There was a decision to keep 06D02 after the Directive 11,000.1 was sent out, so 06D02 is still an applicable procedure code.

### **General- ISP Codes**

#### **question**

What procedure code is used for documenting net weight noncompliance?

#### **answer**

04B03

### **General- ISP Codes**

#### **question**

What procedure code is used for documenting noncompliance with child nutrition programs, declared count, and vignette labeling?

#### **answer**

04B02

### **General- ISP Codes**

#### **question**

What procedure code is used for documentation of noncompliance if more of a non-food safety restricted ingredient is used in a product than is permitted by regulation?

#### **answer**

Use procedure code 04B04 to document the noncompliance.

### **General- ISP Codes**

#### **question**

What procedure code is used to document noncompliance with plant sampling of mechanically separated meat or poultry products?

#### **answer**

FSIS sampling for mechanically separated poultry bone content is recorded under procedure 05B01. If there is noncompliance by the establishment, it is recorded under 04A03.

### **General- ISP Codes**

#### **question**

I found two pieces of spinal cord on the pork neck bones ready to go into the AMRS (reg. 318.24 and FSIS Directive 7160.2). What is the procedure code I should use to document this noncompliance?

#### **answer**

Please follow FSIS Directive 7160.2. You may need to contact your immediate supervisor. The procedure code is 04A03.

### **General- ISP Codes**

#### **question**

If I found noncompliance with regulation 318.7(c)(4) on the amount of proteolytic enzyme solution being added to cuts of meat. What procedure code and trend indicator do I use if the product is not labeled when the procedure is performed?

#### **answer**

The appropriate procedure code is 04A01, and the appropriate trend indicator is economic. If the product were labeled, the same procedure code is used, but the most appropriate trend indicator would be misbranding.

### **General- ISP Codes**

#### **question**

The establishment produces a product that is labeled "Ham and Water Product, 25% of the product is added ingredients." The inspector followed a portion of this production through the process and found that the product contained 30% added ingredients. What procedure code and classification indicator should be used to document the noncompliance? The product was being packaged and labeled when this determination was made.

#### **answer**

The appropriate procedure code is 04A02, and the appropriate trend indicator is misbranding because the product was labeled. If the noncompliance was determined prior to labeling, the most appropriate classification indicator would be economic.

### **General- ISP Codes**

#### **question**

What procedure code and trend indicator would be used to document hydraulic oil found on equipment NOT affecting product?

#### **answer**

Use procedure 06D01 with the structural trend indicator.

### **General- ISP Codes**

#### **question**

I observed condensation on the ceiling, but did not observe it actually fall into or onto exposed product. What procedure code should I use to document this noncompliance?

#### **answer**

Use the procedure code 06D01 with the facilities structural trend indicator marked. Inspection personnel must determine if the situation creates an insanitary condition that leads to product adulteration, or if it is a situation

that is expected to be controlled by the establishment. If product adulteration occurs, the noncompliance would be recorded using the appropriate SSOP procedure code.

## **General-Labeling**

### **General-Labeling**

#### **question**

When product is individually packaged and labeled properly with the net weight, does the shipping container need to identify the product and show the net weight?

#### **answer**

No, neither the product identification nor the net weight need be on the shipping container.

### **General-Labeling**

#### **question**

This company is thinking about slaughtering and labeling products that do not contain antibiotics and growth stimulants. What are the requirements?

#### **answer**

The plant must have a means to verify labeling claims about the raising conditions of the animals from which the products are derived. Food Labeling Division relies on testimonials and affidavits provided by the producer. The affidavits and testimonials must include the producer/s operational protocol which describes, in detail, the production practices employed at the ranch or feedlot that support the labeling claims. If the labeling statements are very general, e.g., "no antibiotics used during raising," the protocol would cover the entire life of the animal from which the product is derived. If a labeling statement on a label for a beef cut conveys that no antibiotics were used during the last 100 days of finishing the animal from which the beef cut was derived, the protocol would include information covering that time period. Such documentation would be submitted to LCPS when label sketch approval is requested. The plant can contact the LCPS (Labeling and Consumer Protection Staff) at 202-205-0623 directly for further questions.

### **General-Labeling**

#### **question**

For procedure 04B04, do we send labels to headquarters to verify accuracy routinely, or only if directed?

#### **answer**

Only if directed by the labeling audit program to send in the labels.

## **General-Non Compliance Records (NR)**

### **General-Non-Compliance Record (NR)**

#### **question**

Do I have to accept the plant's response to an NR when the plant's corrective actions have not corrected the problem?

#### **answer**

No. You do not have to accept the plant's response if the corrective actions did not correct the problem.

### **General-Non-Compliance Record (NR)**

#### **question**

If the establishment responds to an NR with the statement "See attached record" or "See record number\_\_\_\_\_", are those records subject to FOIA?

#### **answer**

Yes. The attached record and the record referred to on the NR response would be available through the Freedom of Information Act (FOIA).

### **General-Non-Compliance Record (NR)**

#### **question**

How much time does FSIS have to issue an NR to the establishment?

#### **answer**

FSIS Directive 5400.5 states that the NR should be issued as soon as possible and at least by the end of the inspector's tour of duty.

### **General-Non-Compliance Record (NR)**

#### **question**

What should I do if I find multiple noncompliance when performing the 06D01 procedure (e.g., holes in the wall and inadequate lighting)?

#### **answer**

There would still only be one NR written describing all the findings and the facility-structural trend indicator would be marked. Inspection personnel are responsible for selecting the most appropriate trend indicator when there are multiple noncompliance found when performing one procedure. All noncompliance should be recorded on one NR when performing one procedure.

## **General-Sanitation Performance Standards**

### **General-Sanitation Performance Standards**

#### **question**

What are the requirements or the process for obtaining USDA approval for

the equipment used in meat or poultry establishments?

**answer**

The USDA Regulations have changed and the equipment approval process is no longer required. Regulation 416.3 and Directive 11,000.1 address the current USDA policy regarding equipment and utensils used in meat and poultry processing plants. Please refer to FSIS Directive 11000.1.

**General-Sanitation Performance Standards**

**question**

Per Dir. 11,000.1, verifying compliance with 416.4 states "In most cases the MSD sheet will substantiate the safety of a chemicals use in a food processing environment." The MSD on a sanitizer used at this plant states, "Causes chemical burns or may cause blindness." It also states problems with breathing, etc., from inhaling the vapor or mist. The plant says that the product is okay to be used at 200ppm on helmets and should not cause any problems. Is the statement by the plant acceptable?

**answer**

We would expect the plant to use the chemical following directions given by the supplier or manufacturer of the product. The directions should state if a rinse is required after use, how to mix the product (PPM allowed), whether or not there can be incidental contact with product, etc. The label on the container may provide the above information also. The MSD sheet is more for safety of personnel.

**General-Sanitation Performance Standards**

**question**

Is it acceptable for a plant to use a sanitizing agent without a potable rinse?

**answer**

The plant is required to follow manufacturing instructions and EPA regulations. Also review FSIS Directive 11,000.1 and the associated Compliance Guidelines.

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### **General-Voluntary Inspection**

#### **General-Voluntary Inspection**

##### **question**

Can I make a cured product out of venison and have it inspected?

##### **answer**

No. First, cure (sodium nitrite/nitrate) is not approved for use in venison. Second, in order for venison to be amenable for inspection, it must contain at least 3% FSIS inspected meat. Amenable product can be cured.

# **HACCP**

## **HACCP- Basic Requirements**

### **HACCP-Basic Requirement**

#### **question**

The plant has 2 different products and 2 HACCP plans. The basic regulatory requirements are met for the first plan. The second plan does not meet all the Basic regulatory requirements. Do I withhold inspection from products covered under the second plan?

#### **answer**

Yes. Inspection would be withheld from the production of products under the plan that doesn't meet the Basic regulatory requirements.

## **HACCP-Corrective Action**

### **HACCP-Corrective Action**

#### **question**

The establishment's HACCP plan states they will calibrate the process-monitoring instruments weekly (using a thermocouple recording device to monitor internal cooked product temperatures at a CCP in smokehouse). If at the end of the week the establishment finds that the thermocouple recording device is not calibrated properly, what action is required of the establishment?

#### **answer**

The establishment would need to provide evidence that demonstrates product measured with this device since the last proper calibration was safe for human consumption. If the establishment cannot produce this evidence, it would need to follow the corrective actions in 417.3(a).

### **HACCP-Corrective Action**

#### **question**

The plant was manufacturing a product in which the HACCP plan did not include a CCP for metal contamination. The plant found metal contamination (possible lead), and product was held by their QC person. The product continues to be retained, and the plant has completed their pre-shipment review for this production lot without any mention of metal contamination. I feel this is a health and safety issue, and should be addressed per 417.3(b) as an unforeseen hazard. In addition, the plant should reassess its HACCP plan.

#### **answer**

Yes. The plant needs to follow regulation 417.3(b).

## **HACCP-Corrective Action**

### **question**

If a monitoring check found a deviation from a critical limit, would the plant have to retain product back to the last acceptable check?

### **answer**

Yes, and the establishment must meet the requirements of 417.3(a) when a deviation from a critical limit occurs.

## **HACCP-Flow Chart**

### **HACCP-Flow Chart**

#### **question**

If I have numerous products with identical flow/process that will all be included the same HACCP plan, can they all be listed on the same flow chart?

#### **answer**

Yes

## **HACCP-Hazard Analysis**

### **HACCP-Hazard Analysis**

#### **question**

If a HACCP plan identifies metal contamination as a hazard, is Directive 7310.4 used to determine the adequacy for detecting and eliminating foreign material?

#### **answer**

If the establishment identifies metal contamination as a hazard that is reasonably likely to occur, a CCP must address eliminating the hazard or reducing it to an acceptable level. If there is a CCP in the HACCP plan for metal contamination, there must be a critical limit at the CCP. Inspection personnel would verify the adequacy of the CCP by performing the HACCP 01 and 02 procedures. FSIS Directive 7310.4 has been cancelled.

## **HACCP-ISP Codes**

### **HACCP-ISP codes**

#### **question**

When performing a HACCP 01 procedure, if noncompliance is determined, it is documented on an NR, and this triggers the HACCP 02 procedure to be performed. If noncompliance is determined during the HACCP 02 procedure, and it takes until the next day (or longer) for the

establishment to finish the process, when is the NR for the 02 procedure issued?

**answer**

The HACCP 02 procedure can not be completed until the pre-shipment review is completed (or the product is shipped). This is the point at which the NR for the 02 can be issued. Remember, in addition to determining if there is noncompliance with a regulatory requirement, the HACCP 02 procedure looks at an entire shipment of product, and therefore is utilized in determining if the HACCP plan prevented distribution of adulterated product.

**HACCP-ISP Codes**

**question**

The HACCP 02 procedure is always performed in response to noncompliance determined during an HACCP 01 procedure. Will the HACCP 02 also be performed as a scheduled procedure?

**answer**

Yes. On average, there are two scheduled HACCP 02 procedures for each scheduled HACCP 01 procedure. Both HACCP 01 and 02 procedures can also be performed as unscheduled procedures.

**HACCP-ISP Codes**

**question**

After HACCP implementation, will more than one inspector be performing the same HACCP procedure at the same time?

**answer**

It is possible that more than one inspector could perform the same procedure code at the same time, but not the same procedure. If an inspector starts performing an HACCP 01 or 02 procedure and is able to complete it, that inspector should perform the entire procedure from start to finish.

**HACCP-ISP Codes**

**question**

If when performing a boneless meat inspection procedure, a public health hazard is observed, which procedure code would we use to document noncompliance?

**answer**

Use the HACCP procedure code for the processing category that applies to the product in question. For example, if the boneless meat was going into fresh beef sausage, the procedure code to use is 03B01 or 03B02 because this is the raw ground processing category.

## HACCP-Monitoring

### HACCP-Monitoring

#### question

What classification indicator should be used if the FSIS inspector finds an unforeseen hazard and writes an NR?

#### answer

Monitoring

### HACCP-Monitoring

#### question

What do I do if the establishment has a continuous system that is not monitored on a continuous basis, and I find a deviation from a critical limit that I am sure the plant will not be able to detect?

#### answer

If the establishment has a continuous system that is not monitored on a continuous basis, and the inspector finds a deviation from a critical limit at a time between the establishment monitoring, and is certain that the plant's process would not detect the deviation, the inspector should provide notification to the establishment. This is the exception to "letting the system work." If this occurs performing the HACCP 01 procedure, it would be documented on an NR as monitoring noncompliance. Then inspection personnel would verify that corrective actions are taken as per 417.3(a) of the regulations as part of the HACCP 02 procedure. If this occurs during the 02 procedure, provide oral notification to the establishment at that time and complete the 02 procedure, including verification of the corrective actions.

## HACCP-Non Compliance (NR)

### HACCP-Non-Compliance Record (NR)

#### question

Who should the NR be addressed to?

#### answer

An NR should be addressed to a person with overall authority to make the corrections necessary as described on the NR. FSIS Directive 5400.5 states that if there is HACCP noncompliance, the NR should be addressed to the person signing the HACCP plan. In the case of SSOP noncompliance, the NR should be addressed to the person signing the SSOP.

## **HACCP- Non-Compliance Record (NR)**

### **question**

The inspector wrote an NR for something that isn't a CCP in our (the plant's) HACCP plan. Can they do that? It was a violation for chilling cooked product.

### **answer**

Yes. NRs are not just written for CCP noncompliance. Any failure to meet the requirements of Part 417 may warrant an NR. It is acceptable for inspection personnel to document noncompliance with the regulatory requirements using the HACCP procedure codes if the noncompliance is food safety related. This is considered as an unforeseen hazard, and the corrective actions in 417.3(b) of the regulations must be implemented by the establishment.

## **HACCP-Plan**

### **HACCP-Plan**

#### **question**

We would like to manufacture some experimental/test products that will be fully labeled prior to shipping. Are these products subject to HACCP?

#### **answer**

Yes, unless this product is "not for sale" and so identified on the finished product label, it is subject to the HACCP regulation.

### **HACCP-Plan**

#### **question**

What are the requirements for "lotting" product under the HACCP regulation?

#### **answer**

The establishment does not have to include their "lotting" procedure in the HACCP plan. The establishment must be able to identify the product represented by the pre-shipment review in pounds, pieces, pallets, etc. The monitoring record must identify the product in some way.

### **HACCP-Plan**

#### **question**

If I follow the time temperature regulation for cooked meat patties for my cooked meat ball product, can I simply state in my HACCP plan that I will follow 318.23?

#### **answer**

First, the plant should determine that the time temperature table in 318.23 eliminates all pathogens of concern in the cooked meatball product. This

may involve historical data from the plant, information acquired from literature reviews, etc. Once this fact is established, the plant could reproduce the time temperature table in 318.23 and incorporate it into their HACCP plan at the CCP for cooking temperature. As a result, the plant would not be restricted to any one of the time temperature combinations in the table, rather any one of the time temperature combinations may be used as a critical limit.

### **HACCP-Plan**

#### **question**

What if the establishment decides to use alternate procedures beyond the parameters of FSIS Directive 6350.1 (e.g., pre-evisceration carcass washes and steam vacuum)?

#### **answer**

FSIS Directive 6350.1 is cancelled in HACCP establishments. The use of steam vacuum and pre-evisceration carcass washes beyond the parameters of FSIS Directive 6350.1 is allowed. However, as part of the plant's validation process, it is expected that the establishment use scientifically validated technology and collect validation data in the plant while using the procedure. These data should be available to FSIS for review.

### **HACCP-Plan**

#### **question**

A religious-oriented canning operation is wondering if they have to be under HACCP since they only produce product that they give away overseas.

#### **answer**

Yes, this operation would be subject to the HACCP regulation.

### **HACCP-Plan**

#### **question**

After I complete all the forms and write my HACCP plan, where do I send it to for approval?

#### **answer**

HACCP plans are not approved by anyone. The HACCP plan belongs to the establishment. There is an awareness meeting that is held between the plant and inspection personnel to familiarize inspection personnel with the plan. The meeting also gives the establishment an opportunity to discuss any concerns about how inspection will be done in this environment. After the awareness process is complete, the inspector will be reviewing the HACCP plan with a basic compliance checklist to determine if the plan meets the basic regulatory requirements.

## **HACCP-Plan**

### **question**

A customer contacted our establishment and asked us to produce and package a product under their label. However, this customer has specific CCPs and critical limits that they want addressed when producing the product. Do we need to amend our current HACCP plan, even if this product is similar to some products already produced?

### **answer**

If the current plan does not address the CCPs required by the customer or the new CLs (critical limits) are not addressed in the HACCP plan, it would have to be amended. The establishment may elect to develop a separate plan for this product. Either way something must be done before the product is produced.

## **HACCP-Plan**

### **question**

Do the HACCP requirements apply to all official establishments?

### **answer**

The HACCP requirements apply to all official establishments that produce meat and poultry products. Official import inspection establishments, ID warehouses, and cold storage warehouses do not produce product and are, therefore, are not currently required to comply with provisions of 9 CFR Part 417. The HACCP requirements also do not apply to the establishments slaughtering and processing animals and birds that are not amenable to the FMIA or PPIA. The Agency recommends that these establishments adopt HACCP on a voluntary basis, however, and intends to include mandatory HACCP for these establishments as part of its regulatory agenda.

## **HACCP-Plan**

### **question**

Since there are only nine processing categories listed in 417.2, can a plant have more than nine HACCP plans?

### **answer**

Yes. The plant can have more than 9 HACCP plans. They can have as many plans as needed. As an example, the plant could have several plans for the fully cooked-not shelf stable processing category if they produce several different products.

## **HACCP-Plan**

### **question**

If a HACCP plan includes both CCPs and CPs, do inspection personnel verify both?

**answer**

There is no regulatory requirement for CPs, but if they are used to meet a regulatory requirement, inspection personnel would verify that the regulatory requirement is met.

**HACCP-Plan**

**question**

The HACCP Basic checklist indicates that the hazard analysis contains hazards that would reasonably be expected to occur. Who determines what hazards are covered in the HACCP plan?

**answer**

The establishment determines what hazards are reasonably likely to occur. We will not make the determination about the scientific validity of the plant's HACCP plan while performing the Basic compliance/noncompliance procedure unless it is obvious that it is not scientifically valid. The plant is responsible for this. If there are questions about the hazard analysis, the District Office should be notified.

**HACCP-Plan**

**question**

Must all public health related procedures be incorporated into the plant's HACCP plan, or is this the plant's decision?

**answer**

When the establishment performs the hazard analysis, if a food safety hazard is found to be reasonably likely to occur, it must be controlled by a CCP somewhere in the process.

**HACCP-Pre Shipment**

**HACCP-Pre-shipment**

**question**

Must the pre-shipment review be performed on all HACCP records?

**answer**

Regulations require that records associated with the production of that product must be reviewed prior to shipment to verify that all critical limits were met at each CCP and corrective actions were taken, if appropriate. 417.5(c). This is explained more fully in FSIS Notice 37-01.

## HACCP-Processing Categories

### HACCP-processing categories

#### question

Can you explain what secondary inhibitors are?

#### answer

Secondary inhibitors do not directly inhibit bacterial proliferation, but cause a change in the product that does inhibit growth of bacteria. For example salt can be added to product in concentrations that reduce the water activity of the product. In this example water activity is the primary inhibitor and the salt that caused the change to the product is the secondary inhibitor.

### HACCP- processing categories

#### question

We are still unclear about the "secondary inhibitors" category listed in the HACCP regulation. What is in these products that is considered the secondary inhibitor?

#### answer

Secondary inhibitors do not directly inhibit bacterial proliferation, but cause a change in the product that does inhibit growth of bacteria. For example, salt can be added to product in concentrations that reduce the water activity of the product. It is not the salt that inhibits the growth, but the lower water activity that inhibits the growth of bacteria. In this example, water activity is the primary inhibitor and the salt is the secondary inhibitor because its addition lowered the water activity in the product. Another way to consider this is the water activity directly inhibits the proliferation while the salt indirectly inhibits proliferation by causing a reduction in the water activity of the product.

## HACCP-Reassessment

### HACCP-Reassessment

#### question

When is the establishment required to reassess its HACCP plan?

#### answer

Regulation 417.4(a)(3) requires that the establishment reassess their HACCP plan at least annually and whenever changes occur that could affect the hazard analysis or alter the HACCP plan. Additionally, 417.3(b)(4) requires reassessment in response to an unforeseen hazard, and paragraph (b)(3)(ii) of 310.25 or 381.94 requires reassessment in response to exceeding the Salmonella performance standards on the second consecutive series of FSIS tests for that product.

## HACCP-Record Keeping

### HACCP-Record Keeping

#### question

The inspector starts at 5 a.m. The establishment employee who handles HACCP records is not available until 6:30 a.m. The inspector wants access to the HACCP records prior to 6:30 a.m. When does the plant have to make HACCP records available to the inspector?

#### answer

The inspector is probably performing procedures shortly after arriving, which in part includes record review. The records should be accessible to inspection personnel during his/her tour of duty.

### HACCP-Record Keeping

#### question

Is there any time limit for a plant to document their corrective action?

#### answer

Corrective actions should be documented at the time they occur. Inspection personnel will need to exercise good judgment in this area because some part of the corrective action may be documented sooner than others. Corrective actions should not be documented until they are performed, but when they are performed they should be documented within a reasonable amount of time.

### HACCP-Record Keeping

#### question

How soon after the monitoring and verification activities do the results have to be recorded on the plant records?

#### answer

Regulation 417.5 requires that each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs.

## HACCP-Records

### HACCP-Records

#### question

The plant cooks large muscle uncured poultry product. They wish to deviate from the recommended cooling guidelines shown in FSIS Directive 7111.1, Appendix B. They have data from Brigham Young University to show they are meeting the stabilization requirements. This data is part of their hazard analysis file. Would they still need a process

authority approval?

**answer**

No. This HACCP plant would only be required to follow the procedure as shown in their data that supports meeting the intent of appendix B. The person who signed off on the HACCP plan could also sign off on this added CCP.

**HACCP-Records**

**question**

Is a plant required to retain documentation related to outdated, replaced parts of the HACCP plan or hazard analysis for a period of time?

**answer**

No, but the establishment should consider that they might still have product in commerce represented by the portion of the plan that was modified, and it would be a good business practice to keep that "old" portion of the plan until that product has left the market. The regulatory retention requirements are for the records generated by the HACCP plan.

**HACCP-Records**

**question**

Should HACCP records be available for all inspection shifts?

**answer**

All records required by the HACCP regulations 417.5 should be available for official review. Inspection personnel on all shifts should have access to these records in a reasonable amount of time. If there are questions concerning the availability of records, these should be addressed through the chain of command. (FSIS Directive 5000.1)

**HACCP-Records**

**question**

If a processing authority is used to evaluate a process, will scientific data supporting his/her decisions be available as part of the HACCP documentation?

**answer**

In those cases where a scientific determination is made by the processing authority, we expect that data to be available, e.g., critical limit not met for time and temperature for cooked beef.

## **HACCP-Training**

### **HACCP-Training**

#### **question**

If a person is trained per 417.7, can they in turn train others in line with 417.7 who then would write the HACCP plans?

#### **answer**

Yes.

### **HACCP-Training**

#### **question**

What are the HACCP training requirements for industry?

#### **answer**

As defined in 417.7, successful completion of a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including segments on the development of a HACCP plan for a specific product, and records review.

## **HACCP-Trend Indicators**

### **HACCP-Trend Indicator**

#### **question**

What classification indicator would be used if it is determined that reassessment requirements are not met?

#### **answer**

Corrective action

## **HACCP-Verification**

### **HACCP-Verification**

#### **question**

I have purchased an infrared device to measure the surface temperature of beef carcasses. The method for calibrating this piece of equipment only ensures a plus or minus 3 degree accuracy. Is this piece of equipment accurate enough to use to monitor this product if I have surface temperature as a CL (critical limit)?

#### **answer**

The regulations do not specify the sensitivity of process monitoring equipment, but it should be sensitive enough to ensure that when performing measurements at a CCP, the critical limit is met. Normally the manufacturer of the process monitoring equipment specifies the calibration procedure and frequency. If the equipment cannot be

calibrated to the sensitivity desired, it might be necessary to build a safety factor into the critical limit to ensure product safety.

### **HACCP-Verification**

#### **question**

Is it acceptable for the establishment to perform verification prior to performing monitoring activities?

#### **answer**

Yes. It would depend on the type of verification activities that are being performed and how the HACCP plan is written. For example, if the establishment has a CCP for metal detection and the critical limit is a certain size particle will be removed from product, the verification activity in the HACCP plan may be to verify that the metal detector is properly calibrated before operations begin. If the verification activity is to make an on-site observation of the monitoring activity, the verification could not take place before the monitoring activity.

### **HACCP-Verification**

#### **question**

Our plant has numerous HACCP plans. We also have numerous smoke/cook houses in operation at the same time that may involve products from 3 or 4 different plans. The monitoring of the cooking operation is conducted by the smoker in each plan. However, our verification of the cooking temperatures is not plan-specific. It is just checking the smoked meats process (cook temperatures), in which once daily a smoke house will be verified for internal product temperature. The inspector feels the verification process should be plan-specific. Is this correct?

#### **answer**

Yes, regulations 417.2(c)(7) require the HACCP plan to list the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with 417.4.

### **HACCP-Verification**

#### **question**

Does the calibration of process monitoring instruments need to be included in the HACCP plan?

#### **answer**

Yes, per regulation 417.4(a)(2)(I).

### **HACCP-Verification**

#### **question**

What must be included in the HACCP plan for verification?

**answer**

The verification procedures and the frequencies of those procedures are to be performed must be included in the HACCP plan. The ongoing verification activities that must be included in the HACCP plan are the calibration of process-monitoring instruments, direct observations of monitoring activities and corrective actions, and the review of records generated and maintained (§417.4). However, ongoing verification activities are not limited to those that are listed in 417.4.

## **SSOP**

### **SSOP- Noncompliance Record (NR)**

#### **SSOP-Non-Compliance Record (NR)**

**question**

If an inspector observes paint chips falling from overhead structures onto exposed product, or pieces of metal in product, would these be addressed as HACCP or SSOP noncompliance?

**answer**

If it is a food safety hazard reasonably likely to occur as determined by the establishment, it would be documented under the HACCP procedure code. If it is product contamination from the facilities, but not food safety related, it would be SSOP noncompliance. For more details, refer to FSIS Directive 11,000.1

### **SSOP-Record Keeping**

#### **SSOP -Record Keeping**

**question**

We wrote an NR yesterday on noncompliance related to a product contact surface. The company performed their corrective action. Today we checked the corrective action record of the company, and they had failed to record the corrective action. We wrote an NR for a records noncompliance. Is this correct?

**answer**

No, the recordkeeping noncompliance would be documented on the same NR with the SSOP failure. The establishment can record their corrective actions on the NR. This is the establishment's option. All the recordkeeping requirements of 416.16 must be met if the NR is used as the record for recording corrective action.

## **SSOP - Record Keeping**

### **question**

Is the plant required to record their monitoring procedures for pre-operational and operational sanitation?

### **answer**

Yes. Regulations 416.16 require the establishment to maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken.

## **SSOP- Trend Indicators**

### **SSOP-Trend Indicator**

#### **question**

What is the appropriate SSOP trend indicator to use if while performing pre-operational sanitation inspection, inspection personnel find product contact surfaces to be contaminated and the establishment did not identify this noncompliance during the monitoring of the pre-operational sanitation procedures?

#### **answer**

Monitoring is the appropriate trend indicator.

### **SSOP-Trend Indicator**

#### **question**

While performing pre-operational sanitation inspection I found corrective action noncompliance and recordkeeping noncompliance. What is the appropriate classification indicator when two types of noncompliance are found?

#### **answer**

The appropriate classification indicator is implementation. The implementation classification indicator is always used in SSOPs when more than one trend indicator is applicable for one procedure. This is applicable to single-inspector and multi-inspector assignments.

## **PROCESSING**

### **Processing-Formulation**

#### **Processing-Formulation**

##### **question**

What percentage of "rework" (for finished snack sticks) is allowed back into new product? Our product is a cooked shelf stable smoked snack

stick.

**answer**

The term "rework" applies to a fully or partially processed product (excluding uncooked trimmings) re-routed for reasons other than unwholesomeness or adulteration (i.e., emulsion residue, product breakage, slicing operations, smoked meats, returns, etc.) and intended for inclusion in cooked sausage, loaves, and similar products. Rework may be used provided it does not adulterate the product, violate its standard of composition, change the order of predominance of ingredients, or perceptibly affect the normal characteristics of the product. Be aware that the regulations place a variety of restrictions on rework. Processors desiring to use rework from semi-dry or dry sausages in other products may submit their written proposal through the area supervisor to FSIS Labeling and Consumer Protection Staff.

**Processing-Formulation**

**question**

Should beef blood be counted towards the meat block when calculating restricted ingredients?

**answer**

Yes, according to the Labeling and Consumer Protection Staff, the blood should be counted towards the meat block.

**Processing-Formulation**

**question**

I have a policy memo on use of sodium lactate in cooked product. Is there any additional information? I have no references on raw product. What are the limits and acceptable uses for sodium lactate and potassium lactate in raw meat/poultry products?

**answer**

A Final Rule published in the January 20, 2000, Federal Register (FR 65, p 3121) amended 9 CFR section 424.21(C) to permit the use of sodium lactate and potassium lactate as antimicrobial agents to inhibit microbial growth in various meat and poultry products (except infant formulas and infant foods) at a level not to exceed 4.8% by weight of the total formulation. Sodium lactate is also listed in 9 CFR Section 424.21(C) as a flow agent in various meat and meat food products, poultry and poultry food products (except in infant formulas and infant foods) at a level not to exceed 2% of product formulation. In a letter to Trumark, Inc. dated November 30, 1999, FSIS indicated that potassium acetate could be used as a flowing agent provided it does not exceed 1.2 % of product formulation.

## **Processing-Labeling**

### **Processing-Labeling**

#### **question**

If a plant is grinding beef and labeling it as ground beef, can they add veal to the product?

#### **answer**

Yes. Veal can be included. However, beef cannot be labeled as veal.

### **Processing-Labeling**

#### **question**

The product's ingredient statement indicates that "sugar" is used. The plant ran out of cane sugar and only has beet sugar on hand to replace it. Can they use the beet sugar?

#### **answer**

Yes, beet sugar can be listed as either "beet sugar" or "sugar" in the ingredients statement on the label.

### **Processing-Labeling**

#### **question**

The establishment makes a frankfurter that contains pork, turkey, chicken and beef. The beef is less than 2 percent of the formulation. They are labeling the product as a "frankfurter made with pork, turkey and chicken." Beef is only disclosed in the ingredients statement. Is this correct?

#### **answer**

Yes, the Labeling Review Branch recently determined that meat or poultry ingredients used at condimental levels (i.e., 2 percent or less) do not recharacterize a product. Consequently, they believe it is misleading to have that species prominently disclosed in the product name. In these situations, the meat or poultry ingredient used at 2 percent or less of the formulation should appear only within the product's ingredients statement in its correct order of predominance.

### **Processing-Labeling**

#### **question**

We produce a ground, battered, breaded, pork pattie that contains some salt, pepper, and sodium phosphate. For years this product has been certified for trichinae. Is this certification still required?

#### **answer**

Yes, as per 318.10(b). Labels should be sent in for review.

## **Processing-Lethality & Stabilization**

### **Processing-Lethality/ Stabilization**

#### **question**

Can the Stabilization Guidelines for products cured with a minimum of 100 ppm nitrite be applied to products such as hams and picnic hams cured with nitrate?

#### **answer**

The guidelines (Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products) in Appendix B specify a minimum of 100 ppm nitrite. The equivalent of nitrate would be applicable for covered products. (Also refer to §424.21(c).)

## **SLAUGHTER OPERATIONS**

### **Slaughter Operations-General-Residues**

#### **Slaughter Operations -General -Residues**

##### **question**

When 05C01 is scheduled, do I take a directed residue sample?

##### **answer**

Directed samples are collected when you receive a directed sample request in the mail. Document it as an 05C01 unscheduled procedure, unless 05C01 is already on the PBIS schedule sheet. If you receive an 05C01 as a scheduled PBIS procedure, and it is necessary to perform an in-plant residue test, then document the procedure as performed. If it is not necessary to perform an in-plant test on that day, document the procedure as not performed. If it is necessary to perform an in-plant residue test and there is no 05C01 on the PBIS schedule sheet, document the test as an unscheduled procedure.

### **Slaughter Operations-General-Zero Tolerance**

#### **Slaughter Operations-General-Zero Tolerance**

##### **question**

Feces was discovered on a beef carcass in the cooler. What action should be taken?

##### **answer**

If the inspector was performing the 03J01 procedure when the fecal contamination was discovered, the establishment would be notified and an NR issued documenting the monitoring noncompliance. If the inspector

was performing the 03J02 procedure when the fecal contamination was observed, the establishment would be notified verbally. In either case the establishment would be expected to evaluate the extent of the situation, and implement the corrective actions of 417.3(a). Inspection personnel would verify that the establishment is meeting the corrective action requirements as part of the 03J02 procedure. If the noncompliance was discovered when performing the 02 procedure, an NR would be issued after the completion of the 02 procedure which means that the pre-shipment review must have been completed or the product shipped.

### **Slaughter Operations- Zero Tolerance**

#### **question**

What are the identification criteria for feces in cattle?

#### **answer**

The following guidelines are utilized in identifying fecal and ingesta contamination. Any foreign material that is characteristically yellow, green or brown in color and has a fibrous or plant material texture should be identified as fecal or ingesta contamination. Size is unimportant in identifying fecal or ingesta, but may be more difficult to discern as size decreases. In livestock, feces and ingesta are not differentiated.

Reference FSIS Directive 6420.1.

### **Slaughter Operations- Zero Tolerance**

#### **question**

What are the verification, documentation, and enforcement procedures when the inspector finds fecal contamination on product after the final rail in red meat or just prior to entering the chiller in poultry slaughter establishments?

#### **answer**

HACCP verification procedures by FSIS inspection personnel are the same in slaughter as in other processes. That is, there is a HACCP 01 and a HACCP 02 procedure, each with (a) recordkeeping and (b) review and observation components. The IIC or off-line inspector performs "HACCP verification" for fecal contamination as part of the overall verification of the HACCP system in slaughter operations. If fecal contamination is found after the final rail in red meat slaughter establishments or on poultry carcasses at the entrance of the chiller or beyond through the performance of FSIS verification procedures, then this is considered a deviation from a critical limit (regardless of the location of the CCP). This is considered monitoring noncompliance, and FSIS will verify corrective actions as per 417.3(a). This is not a system failure at this point. If this is part of an 03J01 procedure then an NR would be issued and the 03J02 procedure would be performed and would verify the

corrective actions as part of this procedure. If this is part of an 03J02 procedure, the establishment is verbally notified of the monitoring noncompliance and the 03J02 procedure is completed, including verification of the corrective actions. An NR is issued upon completion of the 03J02 procedure. A determination of an inadequate system will be made based on repetitive noncompliance with the zero tolerance standard for fecal contamination, and the NRs documenting an ongoing occurrence of failed implementation and/or execution of effective immediate and further planned actions.

### **Slaughter Operations- Zero Tolerance**

#### **question**

What if the establishment decides to use alternate procedures beyond the parameters of FSIS Directive 6350.1 (e.g., pre-evisceration carcass washes and steam vacuum)?

#### **answer**

FSIS Directive 6350.1 is cancelled in HACCP establishments. The use of steam vacuum and pre-evisceration carcass washes beyond the parameters of FSIS Directive 6350.1 is allowed. However, as part of the plant's validation process, it is expected that the establishment use scientifically validated technology and collect validation data in the plant while using the procedure. These data should be available to FSIS for review.

### **Slaughter Operations- Zero Tolerance**

#### **question**

Does zero tolerance apply to chitterlings?

#### **answer**

No, chitterlings are not subject to zero tolerance. However, a finding of feces and/or ingesta on this product means the product is adulterated under the Federal Meat Inspection Act. Therefore, the product will be verified for compliance to Regulation 9 CFR 310.18, and is considered unwholesome.

### **Slaughter Operations- Zero Tolerance**

#### **question**

In a HACCP plant, while performing a zero tolerance check on line #3, I found feces on a chicken carcass. Approximately two hours later, I noticed feces on a carcass on this same line after the washer and prior to the chiller. The plant said that because I found the noncompliance when I was not performing a procedure, the second finding was not a zero tolerance failure. Is this correct?

**answer**

This would also be a zero tolerance failure and the plant must follow 417.3(a). It would be documented on an NR under the 03J02 code, and the system verified by FSIS personnel (i.e. performing all portions of 02 procedures).

**Slaughter Operations- Zero Tolerance**

**question**

This plant operates 4 poultry lines. The plant "lots" its production into two lots per shift. A "lot" is product before and after lunch. If one inspector performs the 10-bird test from each line (total of 40 birds), how is noncompliance documented if the inspector finds fecal contamination on more than one 10-bird test?

**answer**

Noncompliance would be documented under the 03J01 code for the 40 bird check. Since noncompliance was found performing the zero tolerance check, all four parts of the corrective actions of 417.3(a) must be implemented by the establishment and verified by inspection personnel. (See FSIS Directive 6150.1.)

**Slaughter Operations- Zero Tolerance**

**question**

When are urates in poultry considered to be feces for zero tolerance?

**answer**

The definition of feces includes: Color varying from shades of yellow to green, brown and white. The whitish material on the carcasses can come from the cloaca or urinary tract. When whitish material appears on the carcasses other than around the kidneys and their crypts, it is considered fecal material (having passed through the cloaca) and zero tolerance applies. See FSIS Directive 6150.1, Rev. 1.

**Slaughter Operations- Zero Tolerance**

**question**

When the IIC is relieving on-line inspection personnel and sees fecal contamination at the final rail, is that information recorded on an NR or does the IIC perform an off-line procedure? Should the fecal contamination seen while performing the on-line duties be recorded on the NR as justification for performing the off-line procedure?

**answer**

The IIC should perform an off-line procedure just as would occur if the on-line inspector notified him/her of excessive contamination occurring at the final rail. The findings while performing the on-line duties should not be documented. (FSIS Directive 6420.1)

## **Slaughter Operations- Zero Tolerance**

### **question**

The inspector guidelines say to monitor the zero tolerance. What if the plant monitors their zero tolerance fecal checks under GMPs? Can the HACCP procedure code be used when we find noncompliance? If not, what procedure code can be used?

### **answer**

The HACCP procedure code 03J01/03J02 is used to document noncompliance with the zero tolerance standard anytime the off-line inspector finds fecal contamination after the final rail in red meat plants and prior to the chiller in poultry plants. Remember that the Agency has determined that visible fecal contamination is a food safety hazard reasonably likely to occur and therefore it will have to be addressed in some manner in the HACCP plan. How it is addressed is up to the establishment. Remember GMPs cannot take the place of CCPs.

## **Slaughter Operations-Red Meat**

### **Slaughter Operations-Red Meat -Equine**

#### **Slaughter Operations-Red Meat-Equine**

##### **question**

Where can I find a listing of the horse slaughter plants in the U.S.?

##### **answer**

Horse slaughter plants are listed in the "Other Species" list in the Meat and Poultry Inspection Directory. They are identified as "Equine Inspection" on that list.

### **Slaughter Operations-Red Meat -Swine**

#### **Slaughter Operations-Red Meat-Swine**

##### **question**

When the company removes the bladder from the hog and drops it, and some of the contents splashes up on the carcass, what procedure code should you use to document the noncompliance?

##### **answer**

You would not document each occurrence, but if it continued routinely enough, the IIC should be contacted. If you and the IIC agree that this problem occurs frequently, you would write an NR. The procedure code would be 04C01.

# **Poultry**

## **Poultry Slaughter Systems-General**

### **Poultry-Slaughter Systems-General**

#### **question**

What procedure code is used to document noncompliance with line speed regulatory requirements?

#### **answer**

Use the procedure code 06D02 with the structural trend indicator.

## **Poultry Slaughter Systems-NELS**

### **Poultry-Slaughter Systems-NELS**

#### **question**

In HACCP/NELS plant, I regularly identify chickens with bruises, tumors, etc., that have passed the final trim station. What procedure code should be used to document this noncompliance?

#### **answer**

Use the procedure code 04C01.

### **Poultry-Slaughter Systems-NELS**

#### **question**

What about the other tasks/tests that are specific to the plant's approved NELS program, but are decidedly non-public health related? Are inspectors to continue performing the NELS-specific tasks on random basis and code them as 04C01?

#### **answer**

## **Poultry Slaughter Operations-General**

### **Poultry –Slaughter Operations-General**

#### **question**

The FSIS inspector found an intestine in the chiller. What procedure code would be use to document this noncompliance? If there are a subsequent incident(s), is the same procedure code used?

#### **answer**

The procedure code is 4C01. Yes, it is used for subsequent noncompliances of the same type.

## **Poultry - Reprocessing/Salvage**

### **Poultry-Re-processing/ Salvage**

#### **question**

Do FSIS inspection procedures change for off-line salvage procedures in poultry slaughter operations (e.g., turkey osteomyelitis complex -- TOC, air sacculitis)?

#### **answer**

These procedures are considered an extension of postmortem inspection. FSIS inspection for off-line salvage procedures have not changed at this time.